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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/928,272	09/12/1997	MICHAEL J. ISKRA	P-3818	9434

7590 04/27/2009  
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EXAMINER
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MATTER, KRISTEN CLARETTE

ART UNIT	PAPER NUMBER
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3771

MAIL DATE	DELIVERY MODE
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04/27/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 08/928,272	<b>Applicant(s)</b> ISKRA, MICHAEL J.	
	<b>Examiner</b> KRISTEN C. MATTER	<b>Art Unit</b> 3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 17 March 2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1 and 5-9 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 5-9 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

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### **DETAILED ACTION**

This Action is in response to the amendment filed on 3/17/2009. No claims were amended, added or cancelled. Therefore, claims 1 and 5-9 are currently pending in the instant application.

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

**Claims 1, 5, 6, and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Berger et al. (US 3,706,306).**

Regarding claim 1, Berger et al. discloses a one piece collection container assembly comprising an elongate tubular housing (19) having opposed first and second ends (see Figure 5), a solid partition (25) forming a closed bottom positions within said housing between the first and second ends (see Figure 5), said housing defining a volume for specimen collection and containment therein between said first end and said partition (column 3, lines 55-60), said second end forming a false bottom comprising a bottom end below said partition comprising an annular skirt (side walls of tube 19) and a frustoconical bottom comprising an opening (at 38) therein (see column 5, lines 30-35).

To the extent, if any, that a portion of the side walls of tube 19 cannot be considered to be part of said bottom end (i.e., because from Figure 5 it appears that the bottom of tube 25 is in line

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with the frustoconical bottom and the instant invention claims the "bottom end" must lie below said partition), examiner contends that it would have been obvious to one of ordinary skill in the art to decrease the length of blood sample tube 25 such that the rounded bottom of the tube was located higher than the bottom of the outer tube 19 (so that the side walls of 19 could clearly be called an annular skirt included in the "bottom end") in order to decrease the volume of the blood sample tube without altering the outer dimensions of the container/syringe. In addition, it appears as though the device of Berger et al. would perform equally well with the length of the tube 25 being shorter than the straight portion of tube 19. See also *In re Rose*, 220 F.2d 459, 463, 105 USPQ 237, 240 (CCPA 1955), in which the court held that mere changes in size do not patentably distinguish an invention over the prior art.

In addition, Berger et al. discloses a frustoconical bottom (21) as opposed to a semi-spherical bottom as claimed in claim 1. However, Berger et al. discloses that other parts of the tube are semi-spherical and absent a critical teaching and/or a showing of unexpected results from making the bottom semi-spherical, examiner contends that it would have been an obvious design consideration to one of ordinary skill in the art at the time the invention was made to have made the bottom (21) of Berger et al. semi-spherical as a matter of manufacturing preference because the change involves a mere change in shape that would not patentably distinguish the invention over the prior art. Furthermore, it appears as though the device of Berger et al. would perform equally well with a semi-spherical bottom (21) because semi-spherical shapes are well known and commonly used in the art.

Regarding claim 5, the partition disclosed by Berger et al. is arcuate in shape and has at least a partially rounded bottom portion (see Figure 5).

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Regarding claim 6, the partition disclosed by Berger et al. can be considered conical (see Figure 5).

Regarding claim 9, Berger et al. is silent as to the dimensions of the container. However, absent a critical teaching and/or showing of unexpected results from making the container the claimed dimensions, examiner contends that it is an obvious design consideration to one of ordinary skill in the art to make the Berger et al. container the claimed dimensions because those dimensions are commonly used for blood/specimen collection containers. In addition, it appears as though the device of Berger et al. would perform equally well with the claimed dimensions. See also *In re Rose*, 220 F.2d 459, 463, 105 USPQ 237, 240 (CCPA 1955), in which the court held that mere changes in size do not patentably distinguish an invention over the prior art.

**Claims 7 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Berger et al. as applied to claim 1 above, and further in view of Burns (US 5,458,854).**

Berger et al. discloses that the container is made of synthetic plastic material (column 3, line 45) but does not specifically disclose the claimed thermoplastic polymers. However, Burns discloses, in a blood/specimen collection container, a tube made of the claimed thermoplastic polymers (column 5, lines 43-50) so that the specimen may be readily viewed. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to have made the container of Berger et al. from the thermoplastic polymers of Burns in order to allow the sample to be readily viewed. In addition, it appears as though the device of Berger et al. would perform equally well if made of a thermoplastic polymer. See also *In re Leshin*, 227 F.2d 197, 125 USPQ

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416 (CCPA 1960), in which the selection of a material known for its suitability for a given purpose does not patentably distinguish an invention over the prior art.

### ***Response to Arguments***

Applicant's arguments filed 3/17/2009 have been fully considered but they are not persuasive.

In response to applicant's argument that Berger et al. does not teach a false bottom, examiner respectfully maintains that a false bottom is disclosed in Figure 5 at reference character 38 (bottom portion tapers into an open false bottom in the exact same manner described by applicant in Figures 3-4 and on page 9). Applicant mentions tube (25) cannot be a false bottom on page 5 of the arguments, but examiner points out that the opening at 38 is the false bottom and the bottom of tube 25 comprises the partition. Applicant further argues that in the instant invention liquid from the tube does not flow out of or into the false bottom during use, which is contrary to the prior art. Examiner notes that all claims are device claims and there is nothing in the claims limiting the liquid to not flowing through the false bottom specifically during use. When the liquid level of Berger et al. is below the apertures (29-32) or when the seal strip (34) is in place, no liquid flows through the false bottom. Additionally, the device of Berger et al. is in fact used without liquid flowing through the false bottom because the sample is first separated (which is considered "in use") and then the seal strip is slowly peeled away to release the separated specimen's contents into the cup (20) through the false bottom at 38.

***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KRISTEN C. MATTER whose telephone number is (571)272-5270. The examiner can normally be reached on Monday - Friday 9-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571) 272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kristen C. Matter/  
Examiner, Art Unit 3771

/Justine R Yu/  
Supervisory Patent Examiner, Art Unit 3771